UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,548	07/16/2003	Joel D. Oxman	57179US004	8448

32692 7590 04/05/2006

3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,548	OXMAN ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/27/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/01/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Previous Rejections

Unless explicitly maintained infra, all previous rejections are withdrawn.

Anticipation Rejection

Claims 1 and 3 were rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti (USP 5,944,754).

This rejection is maintained and is now applicable to claims 1, 3 and 14-17.

Applicant argues at p. 10 of the Remarks that:

> **"[F]or anticipation under 35 U.S.C. 102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02 (emphasis added).**
>
> **Applicants respectfully submit that amended claims 1 and 3 are not anticipated by Vacanti because such document does not teach each and every aspect of the claimed invention. Vacanti lacks, among other things, a disclosure that "the viscosity of the composition at the treatment temperature is at least about 10 times the viscosity of the composition at the pre-treatment temperature" (e.g., claims 1 and 3, as amended).**

The examiner does not agree.

A reference can teach "every aspect" of an invention without explicitly stating what should be apparent (implicitly) to the skilled artisan. Vacanti, at col. 4, lines 21-24, discloses the use of "temperature dependent hydrogel(s) that solidify or set at body

temperature, e.g., PLURONICS™" (emphasis added). Changing from a liquid to a solid would certainly appear to involve an at least a ten fold increase in viscosity.

Furthermore, the prior art uses substantially the same gels as Applicant.

See, for instance, the passage bridging col. 5, line 61 to col. 6, line 29:

> Temperature-dependent, or thermosensitive, hydrogels can be use in the methods of the invention. These hydrogels must have so-called "reverse gelation" properties, i.e., they are liquids at or below room temperature, and gel when warmed to higher temperatures, e.g., body temperature. Thus, these hydrogels can be easily applied at or below room

temperature as a liquid and automatically form a semi-solid gel when warmed to body temperature. Examples of such temperature-dependent hydrogels are PLURONICS™ (BASF-Wyandotte), such as polyoxyethylene-polyoxypropylene F-108, F-68, and F-127, poly (N-isopropylacrylamide), and N-isopropylacrylamide copolymers.

These copolymers can be manipulated by standard techniques to affect their physical properties such as porosity, rate of degradation, transition temperature, and degree of rigidity. For example, the addition of low molecular weight saccharides in the presence and absence of salts affects the lower critical solution temperature (LCST) of typical thermosensitive polymers. In addition, when these gels are prepared at concentrations ranging between 5 and 25% (W/V) by dispersion at 4° C., the viscosity and the gel-sol transition temperature are affected, the gel-sol transition temperature being inversely related to the concentration. These gels have diffusion characteristics capable of allowing cells to survive and be nourished.

U.S. Pat. No. 4,188,373 describes using PLURONIC™ polyols in aqueous compositions to provide thermal gelling aqueous systems. U.S. Pat. Nos. 4,474,751, '752, '753, and 4,478,822 describe drug delivery systems which utilize thermosetting polyoxyalkylene gels; with these systems, both the gel transition temperature and/or the rigidity of the gel can be modified by adjustment of the pH and/or the ionic strength, as well as by the concentration of the polymer.

Temperature-dependent, or thermosensitive, hydrogels can be use in the methods of the invention. These hydrogels must have so-called "reverse gelation" properties, i.e., they are liquids at or below room temperature, and gel when warmed to higher temperatures, e.g., body temperature. Thus, these hydrogels can be easily applied at or below room

See also working example 2:

> A biocompatible, biodegradable, reverse-thermosensitive copolymer gel was obtained by preparing a 30% weight/volume solution of a PLURONIC™ F127 or F68 block copolymer (both available from BASF). The solution remains in a liquid state at less than 15° C., and solidifies within 5 to 10 minutes as the temperature is increased to over 15° C. Chondrocytes were isolated from the articular surface of calf forelimbs using standard techniques, and added to the hydrogel mixture to generate a final cellular density of about 2 to 6×10^7/ml.

Since both Applicant and the prior art use the same F127 gelling agent in substantially the same proportions, it is reasonable to expect the prior art compositions to inherently undergo the same ten fold or greater increase in viscosity as Applicants'.

Finally, the examiner notes that new claims 14-17 do not require a ten-fold increase in viscosity, and thus are explicitly anticipated.

Regarding newly added claims 14-17, the examiner notes that the prior art, again implicitly, appears to disclose various additives falling within the scope of the various functional classes of components recited therein. The "low molecular weight saccharides" and salts mentioned in the first citation supra promote the "stability" of the gels and increase their adhesiveness, and thus are "stability promoters", as well as "adhesive modifiers", as required by instant claim 14. They would also be osmotic agents and thus would be reasonably expected to be function as "anti-microbial agents" as required by instant claims 15-17.

Furthermore, working example 5 uses a composition comprising a reverse-thermosensitive hydrogel as used in working example 2, seeded with articular cartilage chondrocyte cells which were grown in 5% CO_2 in a media composed of Hamm's F12

and 10% fetal bovine serum (col. 12, lines 4-24). The media thus would inherently contain sodium bicarbonate and various enzymes and salts, while the chondrocyte cells present therein would also contain various acids, salts, enzymes, antimicrobial agents and sodium bicarbonate as well.

Obviousness Rejection

Claims 2 and 4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti (USP 5,944,754).

This rejection is maintained and is now applicable to claims 2, 4-13, 18 and 19.

The prior art is discussed in the "Anticipation" section supra, and teaches administration of thermoreversible gels to the oral cavity via painting with a brush, or by aerosolizing with a "spraying device". The prior art differs from the instant claims insofar as it does not explicitly disclose, *ipsissima verba*, an aerosol container having a propellant, but it does state that "such devices are commonly used in surgery to spray air or water over a desired surface" (col. 8, lines 26-45). Given that the prior art explicitly discloses aerosols and suggests the use of "well known" spraying devices, the use of a device as simple and widely available as an aerosol container containing a propellant would surely have been obvious therefrom.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614